



United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

**Proposed Designation of
Dibutyl Phthalate
(CASRN 84-74-2)
as High-Priority Substance
for Risk Evaluation**

August 22, 2019

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Acronyms and Abbreviations

Term	Description
ACGIH	American Conference of Governmental Industrial Hygienists
AIA	Aerospace Industries Associated
ATSDR	Agency for Toxic Substances and Disease Registry
Biomon.	Biomonitoring
BOD	Biochemical oxygen demand
BP	Boiling point
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
Concen.	Concentration
CWA	Clean Water Act
CPDat	Chemical and Products Database
ECOTOX	Ecotoxicology Database
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
FDA	U.S. Food and Drug Administration
FR	Federal Register
GC	Gas chromatography
HPLC	High performance liquid chromatography
IRIS	Integrated Risk Information System
IUR	Inventory Update Rule
K	Thousand
K _{OC}	Organic carbon-water partition coefficient
K _{OW}	Octanol-water partition coefficient
M	Million

MITI	Ministry of International Trade and Industry
MP	Melting point
NAICS	North American Industry Classification System
NKRA	Not Known or Reasonably Ascertainable
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIH	National Institute of Health
NIOSH	National Institute for Occupational Safety and Health
NR	Not reported
OECD	Organisation for Economic Co-operation and Development
·OH	Hydroxyl radical
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit
POTW	Publicly owned treatment works
PPE	Personal protective equipment
PPM	Parts per million
RCRA	Resource Conservation and Recovery Act
REL	Recommended Exposure Limit
RY	Reporting Year
SOP	Standard Operating Procedure
SMILES	Simplified Molecular-Input Line-Entry System
T _{1/2}	Half-life
TG	Test guidance
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TWA	Time weighted average
USGS	United States Geological Survey
VP	Vapor pressure
WS	Water solubility

1. Introduction

In Section 6(b)(1)(B) of the Toxic Substances Control Act (TSCA), as amended, and in the U.S. Environmental Protection Agency's (EPA) implementing regulations (40 CFR 702.3)¹, a high-priority substance for risk evaluation is defined as a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Before designating prioritization status, under EPA's regulations at 40 CFR 702.9 and pursuant to TSCA section 6(b)(1)(A), EPA will generally use reasonably available information to screen the candidate chemical substance under its conditions of use against the following criteria and considerations:

- the hazard and exposure potential of the chemical substance;
- persistence and bioaccumulation;
- potentially exposed or susceptible subpopulations;
- storage near significant sources of drinking water;
- conditions of use or significant changes in the conditions of use of the chemical substance;
- the chemical substance's production volume or significant changes in production volume; and
- other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

This document presents the review of the candidate chemical substance against the criteria and considerations set forth in 40 CFR 702.9 for a may present risk finding. The information sources used are relevant to the criteria and considerations and consistent with the scientific standards of TSCA section 26(h), including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the *TSCA Work Plan Chemicals: Methods Document* (February 2012) (40 CFR 702.9(b)). EPA uses scientific information that is consistent with the best available science. Final designation of the chemical substance as a high-priority chemical substance would immediately initiate the risk evaluation process as described in the EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (40 CFR 702).

Dibutyl phthalate is one of the 40 chemical substances initiated for prioritization as referenced in the March 21, 2019 notice (84 FR 10491)². EPA has determined that dibutyl phthalate is a suitable candidate for the proposed designation as a high-priority chemical substance. The proposed designation is based on the results of the review against the aforementioned criteria and considerations as well as review of the reasonably available information on dibutyl phthalate, including relevant information received from the public and other information as appropriate.

¹ NOTE: For all 40 CFR 702 citations, please refer to:

<https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol33/xml/CFR-2018-title40-vol33-part702.xml> and <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0108>

² <https://www.federalregister.gov/documents/2019/03/21/2019-05404/initiation-of-prioritization-under-the-toxic-substances-control-act-tsca>

EPA will take comment on this proposed designation for 90 days before finalizing its designation of dibutyl phthalate. The docket number for providing comments on dibutyl phthalate is EPA-HQ-OPPT-2018-0503 and is available at www.regulations.gov.

The information, analysis, and basis for the review of the chemical is organized as follows:

- *Section 1 (Introduction)*: This section explains the requirements of the amended TSCA and implementing regulations – including the criteria and considerations -- pertinent to the prioritization and designation of high-priority chemical substances
- *Section 2 (Production volume or significant changes in production volume)*: This section presents information and analysis on national aggregate production volume of the chemical substance.
- *Section 3 (Conditions of use or significant changes in conditions of use)*: This section presents information and analysis regarding the chemical substance's conditions of use under TSCA.
- *Section 4 (Potentially exposed or susceptible subpopulations)*: This section presents information and analysis regarding potentially exposed or susceptible subpopulations, including children, women of reproductive age, and workers, with respect to the chemical substance.
- *Section 5 (Persistence and bioaccumulation)*: This section presents information and analysis regarding the physical and chemical properties of the chemical substance and the chemical's fate characteristics.
- *Section 6 (Storage near significant sources of drinking water)*: This section presents information and analysis considered regarding the risk from the storage of the chemical substance near significant sources of drinking water.
- *Section 7 (Hazard potential)*: This section presents the hazard information relevant to the chemical substance.
- *Section 8 (Exposure potential)*: This section presents information and analysis regarding the exposures to the chemical substance.
- *Section 9 (Other risk-based criteria)*: This section presents the extent to which EPA identified other risk-based criteria that are relevant to the designation of the chemical substance's priority.
- *Section 10 (Proposed designation)*: Based on the results of the review performed and the information and analysis presented, this section describes the basis used by EPA to support the proposed designation.

2. Production volume or significant changes in production volume

Approach

EPA considered current volume or significant changes in volume of the chemical substance using information reported by manufacturers (including importers). EPA assembled reported information for years 1986 through 2015 on the production volume for dibutyl phthalate reported under the Inventory Update Reporting (IUR) rule and Chemical Data Reporting (CDR) rule³.

Results and Discussion

The national aggregate production volume, which is presented as a range to protect individual site production volumes that are confidential business information (CBI), is presented in Table 1.

Table 1. 1986–2015 National Aggregate Production Volume Data (Production Volume in Pounds)

Chemical ID	1986	1990	1994	1998	2002	2006	2011	2012	2013	2014	2015
Dibutyl Phthalate (84-74-2)	10M to 50M	10M to 50M	10M to 50M	10M to 50M	10M to 50M	10M to 50M	7,005,890	1M to 10M	1M to 10M	1M to 10M	1M to 10M

Note: M = million

Reference: [U.S. EPA \(2013\)](#), [U.S. EPA \(2017\)](#)

Production volume of dibutyl phthalate in 2015, as reported to EPA during the 2016 CDR reporting period, was in the range of 1 million pound to 10 million pounds.

The range of production volume of dibutyl phthalate as reported to EPA has not changed from 2012 to 2015 from 1 million to 10 million pounds, having decreased from 10 million to 50 million pounds consistently reported from 1986 to 2006. The 2011 production volume is also consistent with the 1 million to 10 million pound range reported from 2012 to 2015 (Table 1).

³ Over time, the requirements for reporting frequency, production volume thresholds, and chemical substances under the Chemical Data Reporting (CDR) rule have changed. CDR was formerly known as the Inventory Update Rule (IUR). The first IUR collection occurred in 1986 and continued every four years through 2006. As part of two rulemakings in 2003 and 2005, EPA made a variety of changes to the IUR, including to change the reporting frequency to every five years to address burdens associated with new reporting requirements. Additional changes to reporting requirements were made in 2011, including to suspend and replace the 2011 submission period with a 2012 submission period, return to reporting every four years, and require the reporting of all years beginning with 2011 production volumes. The reporting of production volumes for all years was added because of the mounting evidence that many chemical substances, even larger production volume chemical substances, often experience wide fluctuations in production volume from year to year. In addition, also as part of the 2011 IUR Modifications final rule (76 FR 50816, Aug 16, 2011), EPA changed the name of the regulation from IUR to CDR to better reflect the distinction between this data collection (which includes exposure-related data) and the TSCA Inventory itself (which only involves chemical identification information).

3. Conditions of use or significant changes in conditions of use

Approach

EPA assembled information to determine conditions of use or significant changes in conditions of use of the chemical substance. TSCA section 3(4) defines the term “conditions of use” to mean the circumstances, as determined by the EPA Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

A key source of reasonably available information that EPA considered for determining the conditions of use for dibutyl phthalate was submitted by manufacturers (including importers) under the 2012 and 2016 CDR reporting cycles. CDR requires manufacturers (including importers) to report information on the chemical substances they produce domestically or import into the United States greater than 25,000 pounds per site, except if certain TSCA actions apply (in which case the reporting requirement is greater than 2,500 pounds per site). CDR includes information on the manufacturing, processing, and use of chemical substances. Based on the known manufacturing, processing and uses of this chemical substance, EPA assumes distribution in commerce. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). While EPA may be aware of additional uses, CDR submitters are not required to provide information on chemical uses that are not regulated under TSCA.

For chemical substances under review that are included on the Toxics Release Inventory (TRI) chemical list, information disclosed by reporting facilities in Part II Section 3 (“Activities and Uses of the Toxic Chemical at the Facility”) of their TRI Form R reports was used to supplement the CDR information on conditions of use (Tables 4,5 and 6). There is not a one-to-one correlation between conditions of use reported under CDR and information reported in Part II Section 3 of the TRI Form R because facilities are not required to disclose in their Form R submissions the specific uses of TRI chemical substances they manufactured on-site or imported. In addition to the information disclosed in Part II Section 3 of the TRI Form R, the information pertaining to waste management activities (i.e., disposal/releases, energy recovery, recycling, and treatment) disclosed in other sections of the Form R was also used to supplement the CDR information on conditions of use as shown in Tables 4, 5 and 6. For purposes of this proposed prioritization designation, EPA assumed end-of-life pathways that include releases to air, wastewater, and solid and liquid waste based on the conditions of use.

CDR and TRI Tables

Based on the publicly available⁴ manufacturing information, industrial processing and use information, and consumer and commercial use information reported under CDR, EPA developed a list of conditions of use for the 2016 and 2012 reporting cycles (Tables 2 and 3, respectively).

⁴ Some specific chemical uses may be claimed by CDR submitters as confidential business information (CBI) under section 14 of TSCA. In these cases, EPA has indicated that the information is CBI.

Table 2. Dibutyl Phthalate (CASRN 84-74-2) Categories and Subcategories of Conditions of Use⁵ (2016 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory of Use	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S.EPA (2019a)
	Import	Import	U.S.EPA (2019a)
Processing	Processing as a reactant	Intermediates in all other basic organic chemical manufacturing	U.S.EPA (2019a)
	Processing as a reactant	Plasticizers in wholesale and retail trade	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Solvents (which become part of product formulation or mixture) in all other chemical product and preparation manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Intermediates in asphalt paving, roofing, and coating materials manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Adhesives and sealant chemicals in construction	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Plasticizers in paint and coating manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Intermediates in petrochemical manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Plasticizers in plastic material and resin manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Plasticizers in plastic product manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Functional fluids (closed systems) in printing and related support activities	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Intermediates in rubber product manufacturing	U.S.EPA (2019a)

⁵ Certain other uses that are excluded from TSCA are not captured in this table.

Life-Cycle Stage	Category	Subcategory of Use	Reference
	Processing – incorporating into formulation, mixture, or reaction product	Plasticizers in soap, cleaning compound, and toilet preparation manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Solvents in soap, cleaning compound, and toilet preparation manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Plasticizers in textiles, apparel, and leather manufacturing	U.S.EPA (2019a)
	Processing – incorporating into articles	Plasticizers in adhesive manufacturing	U.S.EPA (2019a)
	Processing – incorporating into articles	Plasticizers in plastics product manufacturing	U.S.EPA (2019a)
	Processing – incorporating into articles	Plasticizers in rubber product manufacturing	U.S.EPA (2019a)
	Repackaging	Laboratory chemicals in wholesale and retail trade	U.S.EPA (2019a)
	Repackaging	Plasticizers in wholesale and retail trade	U.S.EPA (2019a)
	Recycling	Recycling	U.S.EPA (2019a)
Distribution in Commerce ^{a,b}	Distribution in commerce		
Industrial Uses	Non-incorporative activities	Solvent in Huntsman's maleic anhydride manufacturing technology	U.S.EPA (2019a)
Commercial Uses	Adhesives and sealants	Adhesives and sealants	U.S.EPA (2019a)
	Cleaning and furnishing care products	Cleaning and furnishing care products	U.S.EPA (2019a)
	Floor coverings	Floor coverings	U.S.EPA (2019a)
	Laboratory supply	Laboratory supply	U.S.EPA (2019a)
	Paints and coatings	Paints and coatings	U.S.EPA (2019a)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S.EPA (2019a)
	Personal care products	Personal care products	U.S.EPA (2019a)
	Ink, toner, and colorant products	Ink, toner, and colorant products	U.S.EPA (2019a)
Consumer Uses	Adhesives and sealants	Adhesives and sealants	U.S.EPA (2019a)
	Floor coverings	Floor coverings	U.S.EPA (2019a)

Life-Cycle Stage	Category	Subcategory of Use	Reference
Disposal ^a	Disposal		
^a CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage. ^b EPA is particularly interested in information from the public on distribution in commerce.			

Table 3. Dibutyl Phthalate (CASRN 84-74-2) Categories and Subcategories of Conditions of Use⁶ (2012 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory of Use	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S.EPA (2019a)
	Import	Import	U.S.EPA (2019a)
Processing	Processing as a reactant	Intermediates in all other basic organic chemical manufacturing	U.S.EPA (2019a)
	Processing as a reactant	Plasticizers in wholesale and retail trade	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Plasticizers in all other chemical product and preparation manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Plasticizers in plastics material and resin manufacturing	U.S.EPA (2019a)
	Processing – incorporating into formulation, mixture, or reaction product	Plasticizers in construction	U.S.EPA (2019a)
	Processing – incorporating into articles	Plasticizers in adhesive manufacturing	U.S.EPA (2019a)
	Processing – incorporating into articles	Plasticizers in plastics product manufacturing	U.S.EPA (2019a)
	Recycling	Recycling	U.S.EPA (2019a)
Distribution in Commerce ^{a,b}	Distribution in commerce		
Industrial Uses	Non-incorporative activities	Laboratory chemicals in services	U.S.EPA (2019a)
	Non-incorporative activities	Plasticizers in plastics material and resin manufacturing	U.S.EPA (2019a)

⁶ Certain other uses that are excluded from TSCA are not captured in this table.

Life-Cycle Stage	Category	Subcategory of Use	Reference
	Non-incorporative activities	Plasticizers in plastics products manufacturing	U.S.EPA (2019a)
	Non-incorporative activities	Other in wholesale and retail trade	U.S.EPA (2019a)
Commercial Uses	Explosive materials	Explosive materials	U.S.EPA (2019a)
	Adhesives and sealants	Adhesives and sealants	U.S.EPA (2019a)
	Floor coverings	Floor coverings	U.S.EPA (2019a)
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S.EPA (2019a)
	Ink, toner, and colorant products	Ink, toner, and colorant products	U.S.EPA (2019a)
Consumer Uses	Adhesives and sealants	Adhesives and sealants	U.S.EPA (2019a)
	Floor coverings	Floor coverings	U.S.EPA (2019a)
Disposal ^a	Disposal		
^a CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage. ^b EPA is particularly interested in information from the public on distribution in commerce.			

EPA used TRI data to identify additional conditions of use and to supplement CDR information about conditions of use. In addition, TRI information from 2017 is useful for demonstrating that a condition of use reported to CDR in 2015 is still ongoing.

Table 4. Activities and Uses Reported to TRI for Dibutyl Phthalate, Reporting Year 2011

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
	Import	Basic chemical manufacturing	3251
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262
	Produce or import for on-site use/processing	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262

Activity Type	Activity	Industry Group	NAICS Code
	Produce or import for sale/distribution	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
	Produce or import as a byproduct	Basic chemical manufacturing	3251
Process	Process as a reactant	Basic chemical manufacturing	3251
		Plastics product manufacturing	3261
	Process as an article component	Paint, coating, and adhesive manufacturing	3255
		Rubber product manufacturing	3262
		Other fabricated metal product manufacturing	3329
		National security and international affairs	9281
	Process as a formulation component	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262
		Other fabricated metal product manufacturing	3329
		National security and international affairs	9281
	Process – repackaging	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Other chemical product and preparation manufacturing	3259
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
Otherwise Use		Basic chemical manufacturing	3251

Activity Type	Activity	Industry Group	NAICS Code
	Otherwise use – as a chemical processing aid	Plastics product manufacturing	3261
		Rubber product manufacturing	3262
	Otherwise use – as a manufacturing aid	Plastics product manufacturing	3261
	Otherwise use – ancillary or other use	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Plastics product manufacturing	3261
		Cement and concrete product manufacturing	3273
		Other nonmetallic mineral product manufacturing	3279
		Waste treatment and disposal	5622
		National security and international affairs	9281
Waste Management	Disposal/releases	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262
		Other nonmetallic mineral product manufacturing	3279
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
		National security and international affairs	9281
	Energy recovery	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252

Activity Type	Activity	Industry Group	NAICS Code
		Paint, coating, and adhesive manufacturing	3255
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262
		Cement and concrete product manufacturing	3273
		Other nonmetallic mineral product manufacturing	3279
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
	Recycling	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262
		Other nonmetallic mineral product manufacturing	3279
		Other fabricated metal product manufacturing	3329
	Treatment	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Other nonmetallic mineral product manufacturing	3279
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
		National security and international affairs	9281

Table 5. Activities and Uses Reported to TRI for Dibutyl Phthalate, Reporting Year 2015

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
	Import	Basic chemical manufacturing	3251
		Chemical and allied products merchant wholesalers	4246
	Produce or import for on-site use/processing	Basic chemical manufacturing	3251
		Chemical and allied products merchant wholesalers	4246
	Produce or import for sale/distribution	Chemical and allied products merchant wholesalers	4246
	Produce or import as a byproduct	Basic chemical manufacturing	3251
Process	Process as a reactant	Basic chemical manufacturing	3251
	Process as an article component	Paint, coating, and adhesive manufacturing	3255
		Rubber product manufacturing	3262
		Other fabricated metal product manufacturing	3329
		Waste treatment and disposal	5622
	Process as an impurity	Basic chemical manufacturing	3251
		Other fabricated metal product manufacturing	3329
	Process as a formulation component	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Other fabricated metal product manufacturing	3329

Activity Type	Activity	Industry Group	NAICS Code
		Other miscellaneous manufacturing	3399
		National security and international affairs	9281
	Process – repackaging	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
Otherwise Use	Otherwise use – as a chemical processing aid	Basic chemical manufacturing	3251
	Otherwise use – as a manufacturing aid	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Commercial and service industry machinery manufacturing	3333
	Otherwise use – ancillary or other use	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Plastics product manufacturing	3261
		Cement and concrete product manufacturing	3273
		Other nonmetallic mineral product manufacturing	3279
		Waste treatment and disposal	5622
		National security and international affairs	9281
Waste Management	Disposal/releases	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262
		Other nonmetallic mineral product manufacturing	3279

Activity Type	Activity	Industry Group	NAICS Code
		Other fabricated metal product manufacturing	3329
		Commercial and service industry machinery manufacturing	3333
		Other miscellaneous manufacturing	3399
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
		National security and international affairs	9281
	Energy recovery	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Rubber product manufacturing	3262
		Cement and concrete product manufacturing	3273
		Other nonmetallic mineral product manufacturing	3279
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
	Recycling	Textile and fabric finishing and fabric coating mills	3133
		Rubber product manufacturing	3262
		Other nonmetallic mineral product manufacturing	3279
		Other fabricated metal product manufacturing	3329
		Waste treatment and disposal	5622
	Treatment	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252

Activity Type	Activity	Industry Group	NAICS Code
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Other nonmetallic mineral product manufacturing	3279
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
		National security and international affairs	9281

Reference: [U.S. EPA, 2019b](#)

Table 6. Activities and Uses Reported to TRI for Dibutyl Phthalate, Reporting Year 2017

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
		Waste treatment and disposal	5622
	Import	Basic chemical manufacturing	3251
		Chemical and allied products merchant wholesalers	4246
	Produce or import for on-site use/processing	Basic chemical manufacturing	3251
		Chemical and allied products merchant wholesalers	4246
	Produce or import for sale/distribution	Chemical and allied products merchant wholesalers	4246
	Produce or import as a byproduct	Basic chemical manufacturing	3251
		Waste treatment and disposal	5622
Process	Process as a reactant	Basic chemical manufacturing	3251
	Process as an article component	Rubber product manufacturing	3262
		Other fabricated metal product manufacturing	3329
		National security and international affairs	9281
	Process as an impurity	Basic chemical manufacturing	3251
		Other fabricated metal product manufacturing	3329
	Process as a formulation component	Textile and fabric finishing and fabric coating mills	3133
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Chemical and allied products merchant wholesalers	4246
		National security and international affairs	9281
	Process – repackaging	Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622

Activity Type	Activity	Industry Group	NAICS Code
Otherwise Use	Otherwise use – as a chemical processing aid	Basic chemical manufacturing	3251
		Rubber product manufacturing	3262
	Otherwise use – as a manufacturing aid	Commercial and service industry machinery manufacturing	3333
		Basic chemical manufacturing	3251
	Otherwise use – ancillary or other use	Cement and concrete product manufacturing	3273
		Other nonmetallic mineral product manufacturing	3279
		Waste treatment and disposal	5622
		National security and international affairs	9281
Waste Management	Disposal/Releases	Basic chemical manufacturing	3251
		Paint, coating, and adhesive manufacturing	3255
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Other fabricated metal product manufacturing	3329
		Commercial and service industry machinery manufacturing	3333
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
		National security and international affairs	9281
	Energy recovery	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Rubber product manufacturing	3262
		Cement and concrete product manufacturing	3273
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
	Recycling	Rubber product manufacturing	3262

Activity Type	Activity	Industry Group	NAICS Code
	Treatment	Other fabricated metal product manufacturing	3329
		Waste treatment and disposal	5622
		Basic chemical manufacturing	3251
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Other fabricated metal product manufacturing	3329
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
		National security and international affairs	9281

Reference: [U.S. EPA, 2019b](#)

CDR and TRI Summary and Additional Information on Conditions of Use

In the 2016 CDR data, dibutyl phthalate was reported as used in manufacturing, commercial and consumer products. A total of 17 sites reported specific products manufactured, including adhesives and sealants (4), paints and coatings (4), cleaning and furnishing care products (2), floor coverings (2), other plastic and rubber products (2), ink, toner and colorants (1), laboratory supplies (1) and personal care products (1). For industrial and commercial processing and use, a total of 23 sites reported: processing as a reactant (2); processing – articles (3); processing – formulation, mixture, or reaction product (16); processing – repackaging (1); and use – non-incorporative activities (1).

Industrial use of dibutyl phthalate for all other basic organic chemical manufacturing (processing as a reactant) and adhesive manufacturing (processing – incorporation into article) is consistent between the 2012 and 2016 CDR reporting cycles, with one site reporting this use. Three sites reported use in industrial plastics product manufacturing in 2012, but only one site reported this use in 2016 under processing (incorporation into an articles); however, two sites reported use in plastics product manufacturing under a different type of processing (incorporation into formulation, mixture, or reaction product).

Textiles, apparel, and leather manufacturing, soap, cleaning compound, and toilet preparation manufacturing, and printing and related activities are industrial uses of dibutyl phthalate that were reported in 2016, but not 2012.

CDR data show that industrial use of dibutyl phthalate was consistent between 2012 and 2016. Between 2012 and 2016, the number of sites reporting dibutyl phthalate use to CDR for

consumer and commercial adhesives and sealants increased from one to four. Similarly, the number of sites using dibutyl phthalate for floor coverings and plastic and rubber products both increased from one to two. Only one site reported to CDR an unspecified consumer or commercial use of dibutyl phthalate in 2012, but 11 sites did not report a specific use in 2016. Use of dibutyl phthalate in consumer and commercial ink, toner, and colorant products is consistent between the 2012 and 2016 CDR reporting cycles, as is the number of sites reporting consumer/commercial use as NKRA (not known or reasonably ascertainable). One site reported use of dibutyl phthalate for explosive materials in 2012, but the 2016 CDR data does not report this use. Conversely, one site reported use of this chemical for laboratory supplies, four sites reported use for commercial paint and coatings, and one site reported use in commercial personal care products in the 2016 CDR reporting cycle, but not in 2012. CDR data show that consumer and commercial uses are consistent between 2012 and 2016. Consumer uses were also identified in additional databases, which are included in the Exposure Potential section (Section 8).

TRI data reported in Part II Section 3 of the TRI Form R (“Activities and Uses of the Toxic Chemical at the Facility”) were compiled for Reporting Year (RY) 2011, RY 2015, and RY 2017. RY 2011, RY 2015, and RY 2017 reflect the chemical activities at reporting facilities in calendar years 2011, 2015, and 2017, respectively. Each facility filing a TRI Form R discloses activities that apply to the TRI chemical at the facility. The TRI data presented above are from the TRI dataset updated in April 2019. Tables 4, 5, and 6 present the activities and uses reported to TRI by industry group for 2011, 2015, and 2017. Waste management activity type include all industry groups that reported to TRI using each waste management activity for dibutyl phthalate.

The Aerospace Industries Associated (AIA) reported to EPA that the aerospace industry uses dibutyl phthalate and products/formulations containing dibutyl phthalate in the manufacture, operations and maintenance of aerospace products, and that dibutyl phthalate is used in formulations for adhesives, conductive and interior coatings, potting compounds, putties, dye penetrants, and sealants (EPA-HQ-OPPT-2018-0503-0004). The AIA reported that, as a constituent of products, dibutyl phthalate was identified: within epoxy and other plastic adhesives and in conductive and conformal coatings; in adhesives critical to electrical/circuit boards due to its thermal properties and low outgassing properties (an important property for space applications); as a processing aid for crosslinking in cement for acrylic processing; in coatings that dissipate static charges on floor coatings and in fuel tanks, and as propellants within pyrocartridges used in aircraft ejection seat safety systems; and as a plasticizer for rubber-based formulations for fuel containment systems in both military and commercial aircraft (EPA-HQ-OPPT-2018-0503-0004).

The American Coatings Association reported to EPA that dibutyl phthalate is used in plasticizers as an additive in coatings and adhesives, and it is sometimes also found as an impurity in coatings and adhesives (EPA-HQ-OPPT-2018-0503-0003).

Should the Agency decide to make a final decision to designate this chemical substance as a high-priority substance, further characterization of relevant TSCA conditions of use will be undertaken as part of the process of developing the scope of the risk evaluation.

4. Potentially exposed or susceptible subpopulations

Approach

In this review, EPA considered reasonably available information to identify potentially exposed or susceptible subpopulations, such as children, women of reproductive age, workers, consumers or the elderly. EPA analyzed processing and use information included on the CDR Form U. These data provide an indication about whether children or other susceptible subpopulations may be potentially exposed. EPA also used human health hazard information to identify potentially exposed or susceptible subpopulations.

Results and Discussion

At this stage, EPA identified children, women of reproductive age, consumers and workers as subpopulations who may be potentially exposed or susceptible subpopulations for dibutyl phthalate assessment.

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for dibutyl phthalate. The 2012 and 2016 CDR did not report any use of dibutyl phthalate in children's products. EPA also identified potential developmental hazards that would impact any stage of children's development.

Women of reproductive age (e.g., pregnant women per TSCA statute)

EPA identified studies that observed developmental and reproductive effects following exposure to dibutyl phthalate (Section 7, Table 9). Thus, women of reproductive age were identified as a potentially exposed or susceptible subpopulation with respect to dibutyl phthalate.

Consideration of women of reproductive age as a potentially exposed or susceptible subpopulation was also based on exposure because women of reproductive age are potential workers in the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance.

Workers

Please refer to the Exposure Potential section (Section 8) for summary of potential occupational exposures, which EPA indicates that workers are potentially exposed or susceptible subpopulations based on greater exposure.

Consumers

Please refer to the Exposure Potential section (Section 8) for a summary of potential consumer exposures which EPA indicates that consumers are potentially exposed or susceptible subpopulations based on greater exposure.

5. Persistence and bioaccumulation

Approach

EPA reviewed reasonably available information, such as physical and chemical properties and environmental fate characteristics, to understand dibutyl phthalate's persistence and bioaccumulation.

Physical and Chemical Properties and Environmental Fate Tables

Tables 7 and 8 summarize the physical and chemical properties and the environmental fate characteristics of dibutyl phthalate, respectively.

Table 7. Physical and Chemical Properties of Dibutyl Phthalate

Property or Endpoint	Value ^a	Reference
Molecular Formula	C ₁₆ H ₂₂ O ₄	CRC Handbook (Rumble, 2018)
Molecular Weight	278.344 g/mole	CRC Handbook (Rumble, 2018)
Physical State	Liquid	CRC Handbook (Rumble, 2018)
Physical Form	Oily liquid, colorless, faint yellow	HSDB (2015) citing NIOSH (2010)
Purity	Impurities include ca. 0.01% w/w butyl benzoate and ca. 0.01% w/w butan-1-ol	HSDB (2015) citing ECB (2003)
Melting Point	−35 °C	PhysProp Database (U.S. EPA, 2012b)
Boiling Point	340 °C	PhysProp Database (U.S. EPA, 2012b)
Density	1.046 g/mL at 20 °C	HSDB (2015) citing O'Neil (2013)
Vapor Pressure	2.01 × 10 ^{−5} mm Hg at 25 °C	HSDB (2015) citing Donovan (1996)
Vapor Density	9.58 (relative vapor density to air = 1)	HSDB (2015) citing Lewis (2012)
Water Solubility	11.2 mg/L at 25 °C	Mackay et al. (2006) citing Howard et al. (1985)
	4.45–4,500 mg/L	Mackay et al. (2006) citing several sources
	13.3, 14.6, and 5.50 mg/L at 10, 25, and 30 °C (shake flask surface tension measurement)	Mackay et al. (2006) citing Thomsen et al. (2001)
Log K _{ow}	4.50	HSDB (2015) citing Ellington and Floyd (1996)
Henry's Law Constant	1.81 × 10 ^{−6} (atm·m ³ /mol) at 23 °C	HSDB (2015) citing Atlas et al. (1983)
Flash Point	157 °C	ATSDR (2001) citing Weiss (1986)

Property or Endpoint	Value ^a	Reference
Auto Flammability	403 °C (autoignition temperature)	ATSDR (2001) citing NIOSH (1997)
Viscosity	0.203 poise at 20 °C	HSDB (2015) citing Lewis (2007)
Refractive Index	1.490 at 20 °C	HSDB (2015) citing O'Neil (2013)
Dielectric Constant	TBD	TBD
Surface Tension	TBD	TBD

Notes:

^aMeasured unless otherwise noted; K_{OW} = octanol-water partitioning coefficient

TBD = to be determined, if reasonably available. **EPA is particularly interested in information from the public on these properties or endpoints.**

Table 8. Environmental Fate Characteristics of Dibutyl Phthalate

Property or Endpoint	Value ^a	Reference
Direct Photodegradation	$t_{1/2}$ = 3 hours	Mackay et al. (2006) citing Jin et al. (1999)
Indirect Photodegradation	$t_{1/2}$ = 18.4 hours with reaction with $\cdot OH$ radical	Mackay et al. (2006) citing Howard (1989)
Hydrolysis	$t_{1/2}$ = approximately 22 years	ATSDR (2001) citing U.S. EPA (1989)
Biodegradation (Aerobic)	Water: 69% by BOD, 100% by UV-VIS, 100% by GC after 2 weeks at a concentration of 100 ppm unspecified method (most likely Japanese MITI)	NITE (2019)
	Soil: $t_{1/2}$ = 1.8-53 days reported by multiple sources in Mackay et al., 2006 3 days by microorganisms isolated from soil or wastewater; 11–53 days depending on pH, soil type, etc.; <5 days in garden soil; 48–552 hours based on unacclimated aerobic soil grab sample data; 1.8 days at 30 degrees in garden soil; 6.7 days in soil; 11.2 days in soil; 15.8 days in soil	Mackay et al. (2006)
	Sediment: $t_{1/2}$ = 1.0–23 days reported by multiple sources in Mackay et al., 2006	Mackay et al. (2006)
Biodegradation (Anaerobic)	Water: $t_{1/2}$ = 1.19–27.2 days reported by multiple sources in Mackay et al., 2006	Mackay et al. (2006)
	Soil: $t_{1/2}$ = 1–20 days reported by multiple sources in Mackay et al., 2006	Mackay et al. (2006)

Property or Endpoint	Value ^a	Reference
	Sediment: $t_{1/2}$ = 7–30 days reported by multiple sources in Mackay et al., 2016	Mackay et al. (2006)
Wastewater Treatment	56% total removal (0.52% by biodegradation, 55% by sludge adsorption, and 0.04% by volatilization to air; estimated) ^b	EPI Suite (U.S. EPA, 2012a)
Bioconcentration Factor	3.1–21.2 and 5.2–176 at test substance concentrations of 0.05 and 0.015 ppm, respectively (<i>Cyprinus carpio</i>)	NITE (2019)
Bioaccumulation Factor	Accumulation of 1,2-benzenedicarboxylic acid, 1,2-dibutyl ester in the aquatic and terrestrial food chain is limited by biotransformation, which progressively increases with trophic level	ATSDR (2001) citing Staples et al. (1997)
Soil Organic Carbon:Water Partition Coefficient (Log K_{oc})	2.17 (marine sediment/seawater); 0.3010–1.60 (clay and seawater); 4.54 (calculated, sediment-water); 3.14 (soil)	Mackay et al. (2006)

Notes: ^aMeasured unless otherwise noted; ^bEPI Suite™ physical property inputs: Log K_{ow} = 4.50, BP = 340 °C, MP = –35 °C, VP = 2.01×10^{-5} mm Hg, WS = 11.2 mg/L, Henry's Law Constant = 1.81×10^{-6} atm-m³/mol, SMILES: O=C(OCCCC)c(c(ccc1)C(=O)OCCCC)c1; ·OH = hydroxyl radical; GC = gas chromatography; MITI = Ministry of International Trade and Industry, Japan; BOD = biochemical oxygen demand; K_{oc} = organic carbon-water partitioning coefficient

Persistence and Bioaccumulation Summary

Dibutyl phthalate, is a colorless to faint yellow, oily liquid. Based on its vapor pressure (2.01×10^{-5} mm Hg) and Henry's Law Constant (1.81×10^{-6} atm-m³/mole), dibutyl phthalate is expected to volatilize from water and moist soil surfaces, but not dry soils. It is expected to have low mobility in soil (log K_{oc} 3.14).

In aerobic water, dibutyl phthalate degraded by 69 percent over 2 weeks based on biochemical oxygen demand. Aerobic degradation of dibutyl phthalate in soil occurs at a rate that corresponds to half-lives between 1.8 and 3 days. Based on these results, dibutyl phthalate is expected to have high biodegradability. Dibutyl phthalate in the air will be in the particulate form, which will be removed by wet and dry precipitation. Direct photodegradation of dibutyl phthalate occurs at a rate that corresponds to a half-life of 3 hours. In the vapor phase, dibutyl phthalate will react with photochemically produced hydroxyl radicals at a rate that corresponds to a half-life of 18.4 hours. Bioconcentration factors of 3.1–176 indicate that dibutyl phthalate is not bioconcentrated. Bioaccumulation factor data indicate that dibutyl phthalate will be metabolized more rapidly by organisms the higher up the food chain it goes.

6. Storage near significant sources of drinking water

Approach

To support the proposed designation, EPA analyzed each chemical substance, under its conditions of use, with respect to the seven criteria in TSCA section 6(b)(1)(A) and 40 CFR 702.9. The statute specifically requires the Agency to consider the chemical substance's storage near significant sources of drinking water, which EPA interprets as direction to focus on the chemical substance's potential human health hazard and exposure.

EPA reviewed reasonably available information, specifically looking to identify certain types of existing regulations or protections for the proposed chemical substances. EPA considered the chemical substance's potential human health hazards, including to potentially exposed or susceptible subpopulations, by identifying existing National Primary Drinking Water Regulations under the Safe Drinking Water Act (40 CFR Part 141)⁷ and regulations under the CWA (40 CFR 401.15)⁸. In addition, EPA considered the consolidated list of chemical substances subject to reporting requirements under EPCRA (Section 302 Extremely Hazardous Substances and Section 313 Toxic Chemicals), CERCLA (Hazardous Substances), and CAA (Section 112(r) Regulated Chemicals for Accidental Release Prevention). Regulation by one of these authorities is an indication that the substance is a potential health or environmental hazard which, if released near a significant source of drinking water, could present unreasonable risk of injury to health or the environment.

Results and Discussion

Dibutyl phthalate is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations. Under the CWA section 304, dibutyl phthalate is included in the list of total toxic organics (40 CFR 413.02(i))⁹. It is also designated as a hazardous substance in accordance with Section 311(b)(2)(A) of the Federal Water Pollution Control Act.

Dibutyl phthalate is a hazardous substance under CERCLA. Releases of dibutyl phthalate in excess of 10 pounds must be reported (40 CFR 302.4)¹⁰. Dibutyl phthalate is not subject to CAA 112(r).

Dibutyl phthalate is included on the list of hazardous wastes pursuant to the Resource Conservation and Recovery Act (RCRA) section 3001 (hazardous waste number U069) identifying this commercial chemical product as a toxic waste when discarded (40 CFR 261.33)¹¹. RCRA directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.

⁷ <https://www.govinfo.gov/app/details/CFR-2018-title40-vol25/CFR-2018-title40-vol25-part141-subpartA/summary>

⁸ <https://www.govinfo.gov/app/details/CFR-2018-title40-vol31/CFR-2018-title40-vol31-sec401-15>

⁹ <https://www.govinfo.gov/app/details/CFR-1996-title40-vol15/CFR-1996-title40-vol15-sec413-02>

¹⁰ <https://www.govinfo.gov/content/pkg/CFR-2004-title40-vol26/pdf/CFR-2004-title40-vol26-sec302-4.pdf>

¹¹ <https://www.govinfo.gov/app/details/CFR-2018-title40-vol28/CFR-2018-title40-vol28-sec261-33>

7. Hazard potential

Approach

EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health and environmental hazards for dibutyl phthalate (Tables 9 and 10, respectively).

There are very few publicly available assessments for dibutyl phthalate with cited environmental hazard data, EPA used the infrastructure of ECOTOXicology knowledgebase (ECOTOX) to identify single chemical toxicity data for aquatic and terrestrial life ([U.S. EPA, 2018a](#)). It uses a comprehensive chemical-specific literature search of the open literature that is conducted according to the Standard Operating Procedures (SOPs)¹². The environmental hazard information was populated in ECOTOX and is available to the public. In comparison to the approach used to survey human health hazard data, EPA also used a read-across approach to identify additional environmental hazard data for isomers of dibutyl phthalate, if available, to fill in potential data gaps when there were no reported observed effects for specific taxa exposed to the dibutyl phthalate (Table 10).

Potential Human Health and Environmental Hazard Tables

EPA identified human health and environmental hazards based on a review of the reasonable available information on dibutyl phthalate (Tables 9 and 10, respectively).

Table 9. Potential Human Health Hazards Identified for Dibutyl Phthalate

Human Health Hazards	Tested for Specific Effect	Effect Observed	Reference
Acute Toxicity	X	X	Environment Canada (1994) , NTP (2000) , RIVM (2001) , ATSDR (2001) ; NICNAS (2008) , CPSC (2010) , NICNAS (2013) , NICNAS (2016)
Repeated Dose Toxicity	X	X	U.S. EPA (1987) , Environment Canada (1994) , NTP (1995) , NTP (2000) , ATSDR (2001) , ECB (2004) , NICNAS (2008) , CPSC (2010) , NICNAS (2013) , NICNAS (2016)
Genetic Toxicity	X	X	U.S. EPA (1987) , Environment Canada (1994) , NTP (1995) , NTP (2000) , ATSDR (2001) , RIVM (2001) , NICNAS (2008) , CPSC (2010) , NICNAS (2013) , NICNAS (2016)
Reproductive Toxicity	X	X	U.S. EPA (1987) , Environment Canada (1994) , NTP (1995) , NTP (2000) , ATSDR (2001) , ECB (2004) , OEHHA (2007) , NICNAS (2008) , CPSC (2010) , FDA (2012) ; NICNAS (2013) , CPSC (2014) , NICNAS (2016)
Developmental Toxicity	X	X	Environment Canada (1994) , NTP (1995) , NTP (2000) , ATSDR (2001) , OEHHA (2007) , NICNAS (2008) , CPSC (2010) , FDA (2012) ; FDA (2014) ; NICNAS (2013) , CPSC (2014) , NICNAS (2016)

¹² The ECOTOX Standard Operating Procedures (SOPs) can be found at: <https://cfpub.epa.gov/ecotox/>

Human Health Hazards	Tested for Specific Effect	Effect Observed	Reference
Toxicokinetic	X	X	NTP (1995) , NTP (2000) , ATSDR (2001) , RIVM (2001) , NICNAS (2008) , CPSC (2010) , NICNAS (2013) , NICNAS (2016)
Irritation/Corrosion	X	X	NTP (2000) , NICNAS (2008) , NICNAS (2013) , NICNAS (2016)
Dermal Sensitization	X	X	ATSDR (2001) , ECB (2004) , NICNAS (2008) , CPSC (2010) , NICNAS (2013) , NICNAS (2016)
Respiratory Sensitization	X	X	ATSDR (2001) , NICNAS (2008) , CPSC (2010)
Carcinogenicity	X		NTP (1995)
Immunotoxicity			
Neurotoxicity	X	X	NTP (2000) , ATSDR (2001) , NICNAS (2013)
Epidemiological Studies or Biomonitoring Studies	X	X	Environment Canada (1994) , ATSDR (2001) , OEHHA (2007) , CPSC (2010) , NICNAS (2013) , CPSC (2014) , CPSC (2017)

Note: The “X” in the “Effect Observed” column indicates when a hazard effect was reported by one or more of the referenced studies. Blank rows indicate when information was not identified during EPA’s review of reasonably available information to support the proposed designation.

Table 10. Potential Environmental Hazards Identified for Dibutyl Phthalate

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate Dibutyl Phthalate (CASRN 84-74-2)		Isomers of Dibutyl Phthalate (CASRN 84-74-2) NONE		Reference
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
Aquatic	Acute exposure	Vegetation	10	X	—		Adams et al. (1995); Casserly et al. (1983); Chi et al. (2006); Huang et al. (1999); Jonsson and Baun (2003); Kuang et al. (2003); Kühn and Pattard (1990); Li et al. (2015); Nendza and Wenzel (2006); Scholz (1995)
		Invertebrate	26	X	—		Adams et al. (1995); Call et al. (1979); Call et al. (1983); Dixon et al. (1999); Huang et al. (1999); Jonsson and Baun (2003); Kühn et al. (1989); Laughlin et al. (1978); Linden et al. (1979); Liu et al. (2009); Mayer and Ellersieck (1986); Rao and Conklin (1986); Scholz (1994b); Streufert (1977); Tagatz and Stanley (1987); Walker (1984); Yang et al. (2009); Yoshioka et al. (1985)
		Fish	22	X	—		Adams et al. (1995); Buccafusco et al. (1981); Cravedi and Perdu-Durand (2002); E.G. and G. Bionomics (1983); Geiger et al. (1985); Jarmolowicz et al. (2010); Jee et al. (2009); Mayer and Ellersieck (1986); Mayer et al. (1972); Ortiz-Zarragoitia et al. (2006); Scholz (1994a); Xu et al. (2013a); Xu et al. (2013b)
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	4	X	—		Gardner et al. (2016); Higuchi (2002); Lee et al. (2005); Pickford and Morris (1999)

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate Dibutyl Phthalate (CASRN 84-74-2)		Isomers of Dibutyl Phthalate (CASRN 84-74-2) NONE		Reference
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
	Chronic exposure	Vegetation	6	X	—		Chi et al. (2006); Huang et al. (2006); Li et al. (2006)
		Invertebrate	6	X	—		Huang et al. (1999); Kashian and Dodson (2002); Kuhn et al. (1989); Rao and Conklin (1986); Rhodes et al. (1995); Yoshioka et al. (1986)
		Fish	16	X	—		Aoki et al. (2011); Bhatia et al. (2013); Bhatia et al. (2014) Call et al. (1980); Call et al. (1983); Chen et al. (2015); E.G. and G. Bionomics (1983); Jee et al. (2009); Ortiz-Zarragoitia and Cajaraville (2005); Ortiz-Zarragoitia et al. (2006); Padilla et al. (2012); Rhodes et al. (1995); Van den Belt et al. (2003); Weston et al. (2009); Xu et al. (2014)
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	4	X	—		Higuchi (2002); Ohtani et al. (2000); Shen et al. (2011); Sugiyama et al. (2005)

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate Dibutyl Phthalate (CASRN 84-74-2)		Isomers of Dibutyl Phthalate (CASRN 84-74-2) NONE		Reference
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
Terrestrial	Acute exposure	Vegetation	–		–		none
		Invertebrate	8	X	–		Boyd et al. (2016); Do Nascimento Filho et al. (2013); Jensen et al. (2001); Kim et al. (2008); Lenoir et al. (2014); Neuhauser et al. (1985); Samoiloff et al. (1980)
		Vertebrate	2	X	–		Cater et al. (1977); Wilson et al. (2004)
	Chronic exposure	Vegetation	6	X	–		Cai et al. (2008); Hulzebos et al. (1993); Liao et al. (2009); Sun et al. (2015)
		Invertebrate	2	X	–		Du et al. (2015); Jensen et al. (2001)
		Vertebrate	9	X	–		Cater et al. (1977); Chapin et al. (1998); Hardin et al. (1987); Higuchi et al. (2003); Higuchi (2002); Hill et al. (1975); Nishijima et al. (2003); Oishi and Hiraga (1980); Peakall (1974)

The dash indicates that no studies relevant for environmental hazard were identified during the initial review and thus the “Observed Effects” column is left blank. The “X” in the “Observed Effects” column indicates when a hazard effect was reported by one or more of the referenced studies. The “N/A” in the “Observed Effects” column indicates when a hazard effect was not reported by one of the referenced studies’ abstract (full reference review has not been conducted).

8. Exposure potential

Approach

EPA considered reasonably available information to identify potential environmental, worker/occupational, consumer, and general population exposures to dibutyl phthalate.

Release Potential for Environmental and Human Health Exposure

In addition to other required information, a submission of a TRI Form R report must include the quantities of a TRI chemical the facility released on-site to air, water, or land, and the quantities it transferred off-site to another facility for further waste management. On-site release quantities are reported in Part II Section 5 of the TRI Form R, and off-site transfers are reported in Part II Section 6. Waste management activities include: transfers of a TRI chemical in wastewater to a publicly owned treatment works (POTWs) facility or to a non-POTW wastewater treatment facility for the purpose of treatment for destruction or removal; combustion for energy recovery; treatment (treatment includes treatment via incineration for destruction and waste stabilization); recycling; and release, including disposal. During treatment, combustion for energy recovery, or recycling activities, it is possible that some of the quantities of the TRI chemical will be released to the environment.

Worker/Occupational and consumer exposure

EPA approach for assessing exposure potential was to review the physical and chemical properties, conditions of use reported in CDR, and information from the National Institutes of Health Consumer Product Database and the Chemical and Products Database (CPDat) for dibutyl phthalate to inform occupational and consumer exposure potential. The results of this review are detailed in the following tables.

General population exposure

EPA identified environmental concentration, human and environmental biomonitoring data to inform dibutyl phthalate's exposure potential to the general population (Table 13).

Results and Discussion

Release potential for environmental and human health exposure

Aggregated quantities of dibutyl phthalate released on-site to air, water, and land, and aggregated quantities of dibutyl phthalate transferred off-site to POTW and other wastewater treatment facilities (non-POTW) are presented in Table 11 for RY 2011, 2015, and 2017. The table does not include any of the reported quantities pertaining to other waste management activities (e.g., recycling, combustion for destruction) that occurred on-site or off-site during RY 2011, 2015, and 2017. The "Number of Facilities" is the count of unique facilities that filed a TRI Form R report for dibutyl phthalate for RY 2011, 2015, and 2017. The TRI data presented were obtained from the TRI dataset following its update in April 2019.

Table 11. The TRI Data on Dibutyl Phthalate from Reporting Years 2011, 2015, and 2017 Used in this Document to Assess Exposure Potential

Year	Number of Facilities That Reported	Total Quantities Released On-Site to Air (lbs.)	Total Quantities Released On-Site to Water (lbs.)	Total Quantities Released (Disposed of) On-Site to Land (lbs.)	Total Quantities Transferred to POTWs (lbs.)	Total Quantities Transferred to Other (Non-POTWs) Wastewater Treatment Facilities (lbs.)
2011	92	14,982	118	155,374	7,783	382
2015	72	7,157	2	165,351	2,213	0
2017	63	5,628	0	326,942	8,008	0

Note: POTW = publicly owned treatment works

Reference: [U.S. EPA, 2019b](#)

For RY 2017, 63 facilities submitted TRI reports for dibutyl phthalate. The total quantities of dibutyl phthalate these facilities released on-site to air (as fugitive and stack emissions), surface water and land are: 5,628 pounds; 0 pounds; and 326,942 pounds, respectively. These facilities reported 8,008 pounds of the chemical transferred to POTWs and zero pounds transferred off-site to other non-POTW wastewater treatment facilities for the purpose of wastewater treatment. These transfer categories represent two types of off-site transfers for wastewater treatment that may lead to releases from the receiving facilities. They do not include quantities sent off-site for other types of waste management activities that include, or may lead to, releases of the chemical.

Quantities transferred off-site represent the amount of a toxic chemical a facility sent off-site prior to any waste management (e.g., treatment) at a receiving facility. Some of the quantities of dibutyl phthalate received by the non-POTW wastewater treatment facilities may have been released to surface waters or to air during treatment processes at the facilities.

Worker/occupational exposure

Worker exposures to this chemical may be affected by many factors, including but not limited to volume produced, processed, distributed, used, and disposed of; physical form and concentration; processes of manufacture, processing, and use; chemical properties such as vapor pressure, solubility, and water partition coefficient; local temperature and humidity; and exposure controls such as engineering controls, administrative controls, and the existence of a personal protective equipment (PPE) program.

Dibutyl phthalate has an Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) ([OSHA, 2019](#)). The PEL is 5 milligrams (mg)/cubic meter (m³) over an 8-hour work day, time weighted average (TWA). This chemical also has a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) ([NIOSH, 2010](#)) of 5 mg/m³ TWA. The American Conference of Governmental Industrial Hygienists (ACGIH) set the threshold limit value (TLV) at 5 mg/m³ TWA.

Dibutyl phthalate has a vapor pressure of 2.01×10^{-5} mm Hg at 25 °C/77 °F. Experience has shown that inhalation exposure to vapors generated from liquids with vapor pressures below

0.001 mmHg at ambient room temperature conditions may be negligible. Some handling activities of dibutyl phthalate may generate dust, particularly when handled as a dry powder. Workers may be exposed to aerosolized particles.

Dibutyl phthalate is indicated as being used in adhesives and sealants, and paints and coatings. Products used as adhesive and sealants, and paints and coatings may be applied via spray or roll application methods. These methods may generate mists to which workers may be exposed.

Consumer exposure

Dibutyl phthalate is widely used in consumer products, like cosmetics, adhesives, regenerated cellulose, and cellophane ([ECB, 2004](#)). It is present in some home furnishings, paints, vinyl flooring, and floor wax ([ATSDR, 2001](#)). The National Institutes of Health Consumer Product Database and the Chemical and Products Database ([CPDat](#)) reported dibutyl phthalate in many products ranging from adhesives and arts and crafts products to floor polish, paints, and solvents (Table 12). Consumers are likely exposed to dibutyl phthalate in fragrant products containing this chemical, such as household cleaners and auto products ([NICNAS, 2016](#)). The European Chemicals Agency (ECHA) conducted exposure modeling for cosmetics, food, and toys for children and concluded that there is no need for further information or testing or risk reduction measures beyond those which are being applied already ([ECB, 2004](#)). Chronic use of medication with dibutyl phthalate increased the urinary metabolite monobutyl phthalate in patients ([CPSC, 2010](#)).

Table 12. Exposure Information for Consumers

Chemical Identity	Consumer Product Database
	Consumer Uses (List)
Dibutyl Phthalate (84-74-2)	Adhesive, apparel bags, arts crafts products, automotive, automotive care, automotive component, binding, building material, body repair, carpet, carpet cleaner, casting agent, catalyst, cleaner, clipper lubricant/cleaner, clothing, colorant, decor, electrical, electrical insulation, electronics, filler, filler building material, floor cleaner, floor polish, flooring, fluid property modulator, footwear care, footwear, fragrance, grills, hardener, ink colorant, insulation, leather impregnation, lubricant, metal surface treatment, paint, paint binding, paint filler, paint hardener, paint spray, paper impregnation, paper surface treatment, paving, photographic, plastic, plastic filler, plastic hardener, plastic softener, polish, printing, printing ink, rubber, rubber processing, seal material, softener, solvent, sports equipment, stain remover, surface treatment, textile, textile impregnation, toys, viscous liquid building material, wall building material, wood impregnation

Reference: [CPDat](#)

General population exposure

The general population may be exposed to dibutyl phthalate from contaminated air, water, and some foods ([ATSDR, 2001](#); [CPSC, 2010](#)). Air is likely the main source of exposure for the general population, but some exposure may come from consumption of dairy products, fish, and seafood

([ATSDR, 2001](#)). The major source of dietary dibutyl phthalate intake is from consumption of fish ([ECB, 2004](#)). A summary of the studies from peer-reviewed databases is presented in Table 9.

Table 13. Exposure Information for the Environment and General Population

Database Name	Env. Concen. Data Present?	Human Biomon. Data Present?	Ecological Biomon. Data Present?	Reference
California Air Resources Board	no	no	no	CARB (2005)
Comparative Toxicogenomics Database	yes	yes	no	MDI (2002)
EPA Ambient Monitoring Technology Information Center – Air Toxics Data	yes	no	no	U.S. EPA (1990)
EPA Discharge Monitoring Report Data	yes	no	no	U.S. EPA (2007)
EPA Unregulated Contaminant Monitoring Rule	no	no	no	U.S. EPA (1996)
FDA Total Diet Study	no	no	no	FDA (1991)
Great Lakes Environmental Database	yes	no	no	U.S. EPA (2018b)
Information Platform for Chemical Monitoring Data	no	no	no	EC (2018)
International Council for the Exploration of the Sea	yes	no	yes	ICES (2018)
OECD Monitoring Database	no	no	no	OECD (2018)
Targeted National Sewage Sludge Survey	no	no	no	U.S. EPA (2006)
The National Health and Nutrition Examination Survey	no	no	no	CDC (2013)
USGS Monitoring Data –National Water Quality Monitoring Council	yes	no	no	USGS (1991a)
USGS Monitoring Data –National Water Quality Monitoring Council, Air	no	no	no	USGS (1991b)
USGS Monitoring Data –National Water Quality Monitoring Council, Ground Water	yes	no	no	USGS (1991c)
USGS Monitoring Data –National Water Quality Monitoring Council, Sediment	yes	no	no	USGS (1991d)
USGS Monitoring Data –National Water Quality Monitoring Council, Soil	yes	no	no	USGS (1991e)
USGS Monitoring Data –National Water Quality Monitoring Council, Surface Water	yes	no	no	USGS (1991f)
USGS Monitoring Data –National Water Quality Monitoring Council, Tissue	no	no	yes	USGS (1991g)

^a Concen.= concentration

^b Biomon.= biomonitoring

Dibutyl phthalate has been detected in air, surface water and groundwater, sediment, biota, sewage sludge and waste effluents ([Environment Canada, 1994](#); [ECB, 2004](#)), as well as in human breastmilk ([ECB, 2004](#)). The general population's daily exposure to dibutyl phthalate is estimated to be less than 10 µg/kg/d ([CPSC, 2010](#)). Biomonitoring studies measuring dibutyl phthalate from the urine of children, school teachers, and parents indicate that the primary metabolite for dibutyl phthalate was higher in the children when compared with the adults ([CPSC, 2010](#)). The Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) provides modeling for estimation of dermal and inhalation exposure of the general population, including children, from cosmetics ([NICNAS 2013](#)). Modeling for estimated exposures in women, infants, toddlers, and children is also available ([CPSC, 2014](#)) as are models using the NHANES 2005/2006 exposure estimates ([CPSC, 2015](#)). Susceptible subpopulations will respond differently to dibutyl phthalate exposure compared with the general population (see Section 4).

9. Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority

EPA did not identify other risk-based criteria relevant to the designation of the chemical substance's priority.

10. Proposed designation and Rationale

Proposed designation: High-priority substance

Rationale: EPA identified and analyzed reasonably available information for exposure and hazard and is proposing to find that dibutyl phthalate may present an unreasonable risk of injury to health and/or the environment, including potentially exposed or susceptible subpopulations, (e.g., workers, women of reproductive age, consumers, children). This is based on the potential hazard and potential exposure of dibutyl phthalate under the conditions of use described in this document to support the prioritization designation. Specifically, EPA expects that the manufacturing, processing, distribution, use and disposal of dibutyl phthalate may result in presence of the chemical in surface water and groundwater, ingestion of the chemical in drinking water, inhalation of the chemical from air releases, exposure to workers, exposure to consumers and exposure to the general population, including exposure to children. In addition, EPA expects potential environmental (e.g., aquatic toxicity, terrestrial toxicity), and human health hazards (e.g., acute toxicity, repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, neurotoxicity, and observations in epidemiological studies and/or biomonitoring studies).

11. References

Note: All hyperlinked in-text citations are also listed below

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